REMARKS/ARGUMENTS:

Reconsideration of the above identified application is respectfully requested.

In the Office action dated November 15, claims 1, 3-5, 7, 8, 10-12, 14, 16 and 18 are rejected under 35 U.S.C. § 112, second paragraph.

Claims 4, 5, 11, 12, 14 and 18 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Dorson et al. (Journal of Fish Diseases, 1978, 1:309-320; hereinafter "Dorson"), or in the alternative, Dixon et al. (Journal of Fish Diseases, 1983; 6:399-409; hereinafter "Dixon").

Claims 1, 3, 7, 8, 10 and 16 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Arimoto et al. (Aquaculture, 1996, 143: 15-22 (hereinafter "Arimoto")).

Applicants also acknowledge safe receipt of the "Notice of References Cited" (form PTO-892) and cited reference.

In response to the rejections, Applicants has amended the first paragraph of the Specification to add the granted patent number 6,436,702 to that paragraph. Applicant has amended claims 1, 4, 8, and 11 and added new claims 19-22, which are supported by the Specification on pages 18 and 21, respectively. No new matter has been introduced.

Applicants respectfully submit that the amendments of claims 1, 4, 8 and 11 have overcome the rejections under 35 U.S.C. §§ 102(b)/103(a) and 112 for the reasons set forth below.

Claim Rejections Under 35 U.S.C. § 112

Claims 1, 3-5, 7-8, 10-12, 14, 16 and 18 are rejected under 35 U.S.C. § 112, second

paragraph, as being incomplete for omitting essential elements. Specifically, the Examiner alleges that "[i]t is unclear from the claims how an inactivated virus is obtained from a cell line as inactivated viruses are not infectious and do not replicate.

In response to the rejections, Applicant has amended claims 1, 4, 8, and 11 to clarify that the viruses are inactivated after being harvested from the immortal cell line.

Claim Rejections Under 35 U.S.C. § 102/103

Claims 4, 5, 11, 12, 14 and 18 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Dorson et al. (Journal of Fish Diseases, 1978, 1:309-320; hereinafter "Dorson"), or in the alternative, Dixon et al. (Journal of Fish Diseases, 1983; 6:399-409). However, the Examiner acknowledges that "neither Dorson et al. nor Dixon et al. mention the cell line recited in the claims," but believes that "there is no distinguishing difference between the instantly claimed inactivated virus obtained by a particular cell line and the inactivated virus obtained by another cell line that is administered by Dorson et al. or Dixon et al." *See* Office Action at 3-4.

In response to the rejections, Applicant has amended claims 4 and 11 to further clarify that it is NOT the properties of the inactivated IPNV that distinguishing the claimed invention from those described in Dixon and Dorson, but the quantity of the IPNV that can be propagated from the immortal cell line from *Epinephelus coioides* having an ATCC Deposit No. PTA-859 (hereinafter "GF-1 cell line" from those taught in Dorson and Dixon. That is because at the present time, the major problem for producing sufficient vaccine for prevention of IPNV infection is that the quantity of IPNV is insufficient to administer the vaccine in a wide-range application, particularly when immersion method for vaccine application is applied. The claimed

invention resolved this problem by producing sufficient quantity of IPNV through GF-1 cell line. The fact that the GF-1 cell line can produce sufficient quantity of IPNV is further supported by the 132 declaration that Applicant submitted in connection with the previous submission of her Response to the Office Action.

In Dorson, the IPNV was isolated from severely diseased rain-bow trout and cultured in RTG-2 cells (a rain-bow trout gonad cell line). As shown in the "Multiplication in RTG-2 cells" section of the results on pages 316-318, including Figure 6, the wild type of IPNV with an 10^5 inoculum can only produce up to 10^{7-8} pfu/ml of IPNV in RTG-2 cells at 20°C, which is distinctively different from the titer of IPNV produced from the GF-1 cell line, which provides a viral titer of at least about 10^9 $TCID_{50}$/ml at about 20°C when a viral inoculum of 10^3 $TCID_{50}$/ml is inoculated to the GF-1 cell line.

The focus of Dixon is to study the effect of formalin on inactivating IPNV. The IPNV in Dixon is cultivated in BF-2 (bluegill fry) cells and grown at 20°C. There is no indication whatsoever in Dixon that the IPNV cultivated in BF-2 cells grew exponentially, as compared to that shown in Applicant's invention.

To anticipate a claim, each and every element of the claim must be taught, either expressly or inherently, in a single prior art reference. *See e.g.*, *Verdegaal Bros. v. union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference").

Since neither Dorson nor Dixon, alone or in combination, failed to teach or suggest that sufficient amount of IPNV can be produced in their respective method, i.e., using RTG-2 cells

(Dorson) or BF-2 cells (Dixon), Applicant's claimed invention is not anticipated or rendered obvious by Dorson and/or Dixon.

It is also noted that Dorson teaches to inactivate the IPNV by UV and Dixon teaches to inactivate the IPNV by formalin treatment. However, as claimed in claims 20 and 22, Applicant claims the inactivation of IPNV by heat treatment, which is not taught by either Dorson or Dixon.

Claim Rejections Under 35 U.S.C. § 102(b)/103(a)

Claims 1, 3, 7, 8, 10 and 16 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Arimoto et al. (Aquaculture, 1996, 143: 15-22 (hereinafter "Arimoto")). Specifically, the Examiner alleges that "Arimoto et al. anticipate inactivating NNV by various methods obtained from a cell culture and administering the inactivated vaccine to fish, see the Materials and Methods and Discussion section." *See* Office Action at 4. The Examiner acknowledges that "Arimoto et al. do not mention the cell line recited in the claims."

However, unlike what is alleged by the Examiner, Arimoto in fact does not teach the propagation of NNV in a cell culture, instead, the NNV used in Arimoto is purified directed from infected larvae of striped jack. *See e.g.*, "2.1 Virus Preparations" of the Materials and Methods Section on page 16 of Arimoto. That is because Arimoto's study focus on the effect of chemical and physical treatments on the inactivation of the NNV. *See* Title and Abstract of Arimoto on page 15. Therefore, there is no propagation of the virus. In fact, based on common industrial knowledge in the vaccine production field, it is impossible for one to generate sufficient quantity

of virus to be used for vaccine production based on direct isolation and purification of virus from the host.

Since Arimoto fails to teach or suggest that a sufficient quantity of NNV can be produced in order to immunize the susceptible fish, Applicant's claimed invention is not anticipated or rendered obvious over Arimoto.

In view of the foregoing, the objection and rejections have been overcome and the claims are in condition for allowance, early notice of which is requested. Should the application not be passed for issuance, the examiner is requested to contact the applicant's attorney to resolve the problem.

Respectfully submitted,

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